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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,082	07/10/2000	CHENICHERI H. NAIR	5-00	5840

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GREENLEE WINNER AND SULLIVAN P C
5370 MANHATTAN CIRCLE
SUITE 201
BOULDER, CO 80303

EXAMINER

WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
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1619

DATE MAILED: 01/11/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/463,082

Applicant(s)

NAIR ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1. 6) ☐ Other:

DETAILED ACTION

Claims 1-30 are pending. The Preliminary Amendment received July 10, 2000 amended claims 3-4 and 6-9. Claims 23-30 were added by the Preliminary Amendment received July 10, 2000. Claims 1, 2, 11 and 20 were amended by Amendment received November 21, 2001. The entrance of claims 23-25 was requested by the Amendment received November 21, 2001. Because claims 23-30 were added by the Preliminary Amendment of July 10, 2000, claims 23-25 of the Amendment received November 21, 2001, were not entered.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Australia on July 24, 1997. It is noted, however, that applicant has not filed a copy of the Australian application as required.

Election/Restrictions

Because of the Applicant's amendments to claims 1-2 and 11-20, the Lack of Unity - Requirement is hereby withdrawn and an action on the merits follows.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 11-12, 14-15, 17-18, 20, and 22-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The term "plurality" in claims 1 (line 4 and 6), 2 (lines 3 and 6), 3 (line 1), 11 (lines 2 and 4), 12 (line 1), 20 (lines 3 and 6), 22 (line 2), and 23 (line 1) is a relative term which renders

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the claim indefinite. The term "plurality" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Does the term mean 2, does it mean 100, does it mean something else?

(ii) The phrase "capable of" in claims 1 (line 7), 2 (line 6), 20 (line 6), is vague and indefinite, as it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform that function. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

(iii) The term "portion" in claims 1 (line 8), 2 (line 7), and 11 (line 5) is a relative term which renders the claim indefinite. The term "portion" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

(iv) The phrase "source" in claim 2 (lines 1 and 3) is vague and indefinite, as it is not clear what this phrase refers to. Does it refer to an animal, a test tube, a body of water? Does it refer to something else? The specification does not further define this phrase and one of ordinary skill in the art would not be apprised of it.

(v) The phrase "aqueous medium or solution" in claims 4, 5, 12 (line 4), 14, 15, 24 and 25 is vague and indefinite, as it is not clear what difference exists between an aqueous medium and an aqueous solution. The specification does not further define this phrase and one of ordinary skill in the art would not be apprised of the difference.

(vi) The phrase "100 ng or less" in claims 7 (line 2) and 27 (line 2) is vague and indefinite, as it is confusing. Can the dose be zero?

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(vii) Claim 7 ends with two periods. Since claims are limited to one period, this claim is vague and indefinite, as it is not clear what meaning the second period conveys.

(viii) The phrase “discrete particles” in claim 1 (line 4), 2 (lines 3-4), 6 (line 1), 11 (line 2), 26 (line 1) is vague and indefinite, as it is not clear what difference exists between “discrete particles” and “particles”.

(ix) The term "selectively bind" in claim 11 (line 5) is a relative term which renders the claim indefinite. The term "selectively bind" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Does this phrase mean exclusively or does it mean something else?

(x) The phrase “particles selectively bind to fibrin with a binding efficiency greater than the binding efficiency of said particles with other blood plasma proteins” in claim 11 (lines 5-6) is vague and indefinite, as this phrase is confusing. What is the binding efficiency of particles with other blood plasma proteins? Quantitatively, how much greater is “greater”? If the particles selectively bind to fibrin, how do they also bind to other blood plasma proteins?

(xi) The phrase “at least an outer layer of said layers being chemically modified to permit a stable chemical association of the layer with aqueous medium or solution” in claims 12 (lines 3-4) is vague and indefinite. What is a stable chemical association? Out of the vast array of interactions between compounds, what interactions are encompassed by the phrase “chemical association”? What does it mean to permit a stable chemical association? How does one permit chemistry? What chemical modifications are being referred to?

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(xii) The phrase "radiometric" in claim 17 (line 2) is vague and indefinite, as it is not clear what detection technique is being referred to. The specification does not define the term and one of ordinary skill in the art would not be apprised of it.

(xiii) The semi-colon in claim 18 (line 2) is vague and indefinite, as it is not clear if Gd and Au are part of the Markush group.

(xiv) The term "some" in claim 20 (line 6) is a relative term which renders the claim indefinite. The term "some" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Does this mean 2 or 100 or 1000? Or does this mean something else?

(xv) The phrase "fibrin site" in claim 20 (line 8) is vague and indefinite, as it is not clear whether the "fibrin site" is a localized place or whether this phrase encompasses all fibrin.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burch et al. (Nuc. Med. Communications) in view of Chignier et al. (Biomat.) in further view of Watson et al. (WO 93/15768) and Senden et al. (Jn. Of Nuc. Med.).

Burch et al. teach technegas as a new ventilation agent for lung scanning, wherein technegas is an ultra-fine dispersion of technetium-99m labeled carbon. The particle size of

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technegas is disclosed as less than or equal to 5nm and technegas is disclosed as adhering to the walls of the alveoli. A method of imaging is disclosed. The reference fails to teach fibrin and therapeutic drugs. See Summary-Method Section and Discussion Section.

Chignier et al. teach the haemocompatibility and biological course of carbonaceous composites for cardiovascular devices. It is disclosed that in the presence of blood, fibrin meshes form over carbon-coated implants. See entire document.

Watson et al. teach the use of non-diamond carbon allotropes, such as fullerenes, graphite carbons and amorphous carbons, in diagnostic and/or therapeutic agents. As therapeutic agents, the non-diamond carbon allotropes are disclosed as being used to carry and release therapeutically active molecules or atoms. ^{99m}Tc is disclosed as a radionuclide complexed with non-diamond carbon allotropes. In vivo and in vitro use is disclosed, as are methods of imaging and treatment methods. Aqueous medias and solutions are disclosed as carriers. See pg. 1; pg. 3-pg. 15; pg. 18-pg. 19; pg. 23; pg. 25-pg. 29.

Senden et al. teach the physical and chemical nature of technegas, wherein technegas is a radiotracer in lung ventilation scintigraphy. The average particle size of technegas is disclosed as about 5nm. It is disclosed that there is suggestion that technegas contains discrete radio-labeled fullerenes.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Burch et al. using the teachings of Chignier et al. and obtain a detectable reagent for detecting fibrin because a) both Burch and Chignier teach carbonaceous compounds for use in the cardiovascular bloodstream and b) Chignier teaches his carbonaceous compounds, the carbon coated surface of the implant, as completely covered by a fibrin mesh;

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thus, since Chignier teaches the binding of fibrin to carbon in the cardiovascular bloodstream one would expect technegas, the carbonaceous compounds of Burch, to have similar properties; hence, utilizing technegas to bind to fibrin would be within the skill of one in the art.

Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of the combined references using the teachings of Watson et al. and Senden et al. and obtain a method of targeting a drug to a fibrin site because a) the combined references teach graphite carbons as diagnostic agents; b) and Watson teaches that carbon-based macromolecular structures, such as fullerenes, graphite carbons and amorphous carbons can be used as diagnostic agents combined with radionuclides, therapeutic agents combined with drugs and a combination diagnostic/therapeutic agent, hence teaching the interchangeability of diagnostic and therapeutic agents; b) and furthermore, Senden teaches that there is suggestion that technegas contains discrete radio-labeled fullerenes; thus, one would expect technegas and fullerenes to have similar properties; hence, the use of technegas as a therapeutic agent would be within the skill of one in the art.

The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Prior Art

The prior art made of record and not specifically relied upon in any rejections cited above is either 1) considered cumulative to the prior art that was cited in a rejection or is 2) considered pertinent to the applicant's disclosure and shows the state of the art in its field but is not determined by the Examiner to read upon the invention currently being prosecuted in this application.

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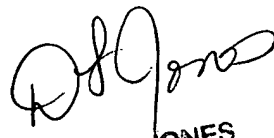
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on T-F (6-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mina Moezie can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
January 2, 2002


DAMERON L. JONES
PRIMARY EXAMINER